Reg. No. : | | | | | | | | | | | | |

Question Paper Code: UC309

B.E./B.Tech. DEGREE EXAMINATION, APRIL / MAY 2025

Professional Elective

Biotechnology

21BTV309 – CLINICAL TRIALS

(Regulations 2021)

Duration: Three hours | Maximum: 100 Marks

Answer ALL Questions

PART A - (10 x 2 = 20 Marks)

1.	Define sampling.	CO1- U
2.	Predict the importance of preclinical trial.	CO3- App
3.	Highlight the significance of zebra fish in clinical research.	CO2- U
4.	Expand INSA & ICMR.	CO2-U
5.	Differentiate the role of sponsors and investigators.	CO1- U
6.	State the principle of good clinical practice.	CO2- U
7.	Categorize 2 essential documents that are to be prepared before the start of a clinical trial.	CO1- U
8.	Mention the components of a Master file.	CO2- U
9.	State the principle of risk management.	CO2- U
10.	Emphasize the opportunities for pharmacovigilance.	CO2- U

PART – B (5 x 16= 80 Marks)

11.	(a)	With a neat flow sheet, comprehend the stages in drug discovery and development process. Comment on the timelines and regulatory bodies involved in the process in India.	CO1- U	(16)
		Or		
	(b)	Explain the importance of clinical trial and summarize the reasons and procedures for premature termination of trials.	CO1- U	(16)

12.	(a)	Paraphrase the principles of ethics to be followed in experiments involving human subjects in India.	CO2- U	(16)
		Or		
	(b)	Comment on methods to reduce the use of animals in research and address the role of animals in research using relevant examples.	CO2- U	(16)
13.	(a)	Comprehend the need for harmonized guidelines for registration of pharmaceuticals for human use. Add notes on the organizational structure and functions of International Conference on Harmonization.	CO1- U	(16)
		Or		
	(b)	Discuss about clinical trials and clinical trial investigator.	CO1- U	(16)
14.	(a)	Prepare an informed consent form for a clinical trial planned for disease X in Hospital Y. Describe the essential components of the informed consent form with relevant examples.	CO4- App	(16)
		Or		
	(b)	Dr.Roy has discovered a new drug to cure Type II diabetes. He is now in need to start a clinical trial to validate invention. Help him out in preparing the essential documents before he starts a trial.	CO4- App	(16)
15.	(a)	Elucidate the principles of clinical trial project management and risk management strategies in clinical trial.	CO2 - U	(16)
		Or		
	(b)	Paraphrase on the organizational structure and responsibilities of Pharmacovigilance Program in India (PvPI).	CO1- U	(16)